APR 2 0 2001

K003809

510(k) Summary (21 CFR Part 807.92)

Product: Rapid Amphetamine, Benzodiazepines, Cocaine, THC, Opiate, Methamphetamine and Phencyclidine Test Strips and DOA Multiple Drug Test Cards (up to six tests).

Name of Manufacturer: Rapid Diagnostics, Inc. 1429 Rollins Road, Burlingame, California, USA

Principle: The Rapid Drug tests are based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for antibody binding between drug conjugate and free drug which may be present in the urine specimen being tested.
When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, 1000 ng/ml, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

Intended Use: The Rapid Drug tests are immunochromatography based one step in vitro test. It is designed for qualitative determination of amphetamine, benzodiazepines, cocaine, THC, opiate, methamphetamine and phencyclidine in human urine specimens above the following cut-off level:

Amphetamine	1000 ng/ml
Benzodiazepines	300 ng/ml
Cocaine	300 ng/ml
THC	50 ng/ml
Opiate	300 ng/ml
Methamphetamine	1000 ng/ml
Phencyclidine	25 ng/ml

Performance: The studies performed are listed below: sensitivity, precision, reproducibility, accuracy (comparison study of clinical urine specimens), product and specimen stability, interference and specificity. Both urine control specimen and clinical urine specimen were tested to evaluate the safety and effectiveness of Rapid Drug Test Panels. The results of performance characteristics demonstrate the Rapid Drug Tests to be substantially equivalent to the SureStep Drugs Screen Panels which received 510k approvals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 0 2001

Mr. Charles Yu
President
Rapid Diagnostics, Inc.
1429 Rollins Road
Burlingame, CA 94010

Re: 510(k) NUMBER: K003809

Trade/Device Names: Rapid Amphetamine Test Strip
Rapid Benzodiazepines Test Strip
Rapid Cocaine Test Strip
Rapid THC Test Strip
Rapid Opiates Test Strip
Rapid Methamphetamine Test Strip
Rapid Phencyclidine Test Strip
Rapid DOA-2, DOA-3, DOA-4, DOA-5 and DOA-6
Multiple Test Panels

Regulation Number: 862.3100, 862.3610, 862.3170, 862.3870, 862.3250, 862.3650
Regulatory Class: II
Product Code: DKZ, DJC, JXM, LDJ, DIO, DJG
Dated: March 20, 2001
Received: March 22, 2001

Dear Mr. Yu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K003809

Device Name: Rapid Amphetamine Test Strip

Indications For Use:

The Rapid AMP Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of amphetamine and in human urine specimens above a cut-off level of 1000 ng/ml.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003809

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): _____

Device Name: Rapid Benzodiazepines Test Strip

Indications For Use:

The Rapid BZO Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of benzodiazepines and its metabolites in human urine specimens above a cut-off level of 300 ng/ml.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

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Division of Clinical Laboratory Devices
510(k) Number K003809

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): _____

Device Name: Rapid Cocaine Test Strip

Indications For Use:

The Rapid COC Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of cocaine's metabolite, benzoylecgonine, in human urine specimens above a cut-off level of 300 ng/ml.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
(510(k) Number K060259

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): _____

Device Name: Rapid THC Test Strip

Indications For Use:

The Rapid THC Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of THC and its metabolites in human urine specimen. The present of 11-nor-Δ^9-COOH in human urine above a cut-off level of 50 ng/ml can be detected.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

Sign-Off)
of Clinical Laboratory Devices
Number K003809

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): _____

Device Name: Rapid Opiates Test Strip

Indications For Use:

The Rapid Opiates Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of Opiates and its metabolites in human urine specimen. The presence of Opiates in human urine above a cut-off level of 300 ng/ml can be detected.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003589

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): _____

Device Name: Rapid Methamphetamine Test Strip

Indications For Use:

The Rapid METHAMP Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of methamphetamine and its metabolites in human urine specimen above a cut-off level of 1000 ng/ml.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003849

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): _____

Device Name: Rapid Phencyclidine Test Strip

Indications For Use:

The Rapid PCP Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of Phencyclidine in human urine specimen. The presence of PCP in human urine above a cut-off level of 25 ng/ml can be detected.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
(510(k) Number K003809

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): _____

Device Name: Rapid DOA-2, DOA-3, DOA-4, DOA-5 and DOA-6 Multiple Test Panels

Indications For Use:

All of Rapid DOA Test Panels are the immunochromatography based one step in vitro test. It is designed for qualitative determination of drug of abuse substance in human urine specimen.

The following component strips are used for the combinations of DOA multiple test panels, the cot-off concentration level of each strip are listed below:

Amphetamine	**1000**	**ng/ml**
Benzodiazepines	**300**	**ng/ml**
Cocaine	**300**	**ng/ml**
THC	**50**	**ng/ml**
Opiates	**300**	**ng/ml**
Methamphetamine	**1000**	**ng/ml**
Phencyclidine	**25**	**ng/ml**

Each multiple test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003869

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)